UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,058	03/17/2004	Anuj Chauhan	T2315-908542US02	1707

181 7590 12/16/2011

MILES & STOCKBRIDGE PC
1751 PINNACLE DRIVE
SUITE 500
MCLEAN, VA 22102-3833

EXAMINER	
BERRIOS, JENNIFER A	

ART UNIT	PAPER NUMBER
1613	

NOTIFICATION DATE	DELIVERY MODE
12/16/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocketing@milesstockbridge.com
sstiles@milesstockbridge.com

Office Action Summary	Application No.	Applicant(s)	
	10/802,058	CHAUHAN ET AL.	
	Examiner	Art Unit	
	JENNIFER BERRIOS	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-21* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-21* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the reply 11/8/2011

Currently claims 1-21 are pending examination.

Declaration

The declaration of Anuj Chauhan and Derya Gulsen filed 11/18/2011 is acknowledged and has been considered. The declaration is persuasive, as such the rejections presented in the office action mailed 8/18/2011 have been withdrawn.

New Rejections

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 5, 7-9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neefe (US 3,786,812), Ding (PSTT, Vol. 1, No. 8, Nov 1998), Nagarsenker et al (Int. Journal of Pharmaceutics 190 (1999) 63-71) , Evitts et al (EP 0 480 690).

Neefe teaches a contact lens for ocular delivery. The central segment being transparent and capable of correcting refractive errors (Abs). The release rate of the drug can be controlled by different methods, such as microencapsulation of the drug, solubility of the drug in water, dispersing the drug in a particle to form a matrix, and more. One of ordinary skill in the art would recognize these methods of controlling release to be functional equivalents, as they are taught by the art to be useful for the same purpose, and could therefore be combine to create a third method of controlling, for example the drug could be microencapsulated within the lens and subsequently dispersed within a particle.

MPEP 2144.06 recites "*It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).*"

Regarding claim 20: A suitable drug for use is pilocarpine

Regarding claim 9: Although Neefe does not teach placing the contact lens on the eye of a patient, it would have been prima facie obvious to use the contact lens for its intended purpose, to deliver drugs to the eye.

Neefe does not teach the drug to be a nanoparticle. However, Ding demonstrates that it's well known in the art that nanoparticles can be utilized, which provide sustained drug release and prolonged therapeutic activity for the delivery of either hydrophobic or hydrophilic ophthalmic drugs (Pg. 332-333). Furthermore controlled particle size and control of the rate of the drug release must be further examined.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Neefe and Ding, as one of skill in the art would have recognized that nanoparticles could be used as the particles of Neefe, as Ding demonstrates that these are well-known in the art to be used for controlled drug release of ophthalmic drugs. Absent evidence to the contrary one of skill in the art would have a reasonable expectation of success, as Neefe and Ding teach the use of particles for the controlled release of ophthalmic drugs.

Neefe/Ding fail to teach the ophthalmic drug nanoparticles to be encapsulated with an encapsulation material selected depending on the drug characteristic (hydrophobic or hydrophilic), such as liposomes or micro emulsions as recited by instant claims 1, 5 and 8.

Nagarsenker teaches the preparation and evaluation of liposomal formulations for ocular delivery, which can serve as a slow release depot. Ophthalmic drugs were entrapped in liposomes. Liposomes have the ability to entrap hydrophilic compounds in the aqueous compartment and to incorporate hydrophobic molecules in the lipid bilayers (Pg. 64).

Evitts teaches an ophthalmic composition comprising oil in water micro emulsion. The micro emulsion is used to encapsulate tepoxalin, which is nearly insoluble in water (i.e. hydrophobic). A micro emulsion is a translucent to a transparent composition and is usually stable (Pg. 1)

It would have been prima facie obvious to one of skill in the art at the time the invention was made to combine to teaching of Neefe/Ding and Nagarsenker/Evitts to arrive at the instant

invention. One of skill in the art would have been motivated to select one of the encapsulations materials, micro encapsulation or liposomes as taught by Evitts and Nagarsenker depending on the drug utilized in the nanoparticles, hydrophobic or hydrophilic, as Evitts teaches that micro emulsions make lipophilic drugs more soluble and stable. Finally one of skill in the art would expect reasonable success because Neefe/Ding/Nagarsenker and Evitts all teach ocular drug delivery compositions.

6. Claims 4, 10-12 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neefe (US 3,786,812), Ding (PSTT, Vol. 1, No. 8, Nov 1998), Nagarsenker et al (Int. Journal of Pharmaceutics 190 (1999) 63-71), Evitts et al (EP 0 480 690), as applied to claims 1, 5, 7-9 and 20 above, and further in view of Benz et al (US 5,891,932) and Jessen (US 4,925,017).

7. Neefe/Ding/Nagarsenker/Evitts teach all the limitations of claims 1, 5, 7-9 and 20, but do not teach the contact lense to comprise p-HEMA nor be part of a kit.

8. Benz teaches that contact lenses made with 2-hydroxyethylmethacrylate (p-HEMA) have excellent properties, such as good strength, excellent water retention properties and excellent dimensional stability (Abs).

Jessen teaches a contact lens storage kit, wherein the lens is stored in a saline solution.

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Neefe/Ding/Nagarsenker/Evitts and Benz/Jessen. One of skill in the art would have recognized that the contact lens of Neefe could be made with p-HEMA and would be motivated to do so, as Benz teaches that contact lenses made with p-HEMA have excellent properties, such as good strength and stability.

Neefe and Benz are silent to the phrase "optically transparent", however the definition of said term in applicant's specification states, "a degree of transparency equivalent to that of p-

HEMA or other material employed as a contact lens". The materials taught in Benz read on said definition.

Regarding claims 10-11 and 14-15: Neefe is silent to the particulars of the kit claimed in the instant claims.

It is well within the knowledge of one of ordinary skill in the art to include a kit or article of manufacture in combination with the contact lens of Neefe because they provide a convenient mechanism to disperse products to consumers. Additionally, labels containing indications, directions, warnings, etc. are mandated. A practitioner would reasonably expect a kit comprising the drug delivery system of Neefe to provide a convenient mechanism to disperse the product to consumers as well as inform the consumer of indications, directions, and so on. Therefore, in Neefe it would have been obvious to one of ordinary skill in the art to package and label delivery system in a kit or article of manufacture, as demonstrated by Jessen, who teaches that contact lens storage kits are well-known.

It is also well within the knowledge of one of ordinary skill in the art to include a drug-saturated solution in the kit so the drug does not diffuse out of the contact lens and become diluted. A practitioner would reasonably expect the contact lens to have a therapeutically effective amount or concentration of drug. Therefore, in Neefe it would have also been obvious to one of ordinary skill in the art to include a drug-saturated solution in a kit or article of manufacture.

9. Claims 6 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neefe (US 3,786,812), Ding (PSTT, Vol. 1, No. 8, Nov 1998), Nagarsenker et al (Int. Journal of Pharmaceutics 190 (1999) 63-71), Evitts et al (EP 0 480 690), as applied to claims 1, 5, 7-9 and 20 above, and further in view of Darouger et al (US 6,264,971).

Neefe/Ding/Nagarsenker/Evitts teach the elements of claim 1, but are silent to the particular ophthalmic drugs recited in claims 6 and 17-19.

Darougar teaches an ocular insert that releases an ophthalmic drug in a controlled, sustained fashion (abstract). Said ophthalmic drugs include antibiotics such as gentamycin, anti-microbial drugs, anti-inflammatories such as prednisolone acetate, non-steroidal agents such as diclofenac (i.e., Voltaren), pilocarpine and timolol (col. 5, line 41 – col. 6, line 16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute said particular ophthalmic drugs for the drug of Neefe with a reasonable expectation of success because the prior art suggests that a) said drugs are well-known for the purpose of treating the eye an can be used in controlled release devices.

10. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neefe (US 3,786,812), Ding (PSTT, Vol. 1, No. 8, Nov 1998), Nagarsenker et al (Int. Journal of Pharmaceutics 190 (1999) 63-71), Evitts et al (EP 0 480 690), as applied to claims 1, 5, 7-9 and 20 above, and further in view of Higuchi et al (US 4,052,505).

Neefe/Ding/Nagarsenker/Evitts teach the elements of claim 1, but are silent to the particular ophthalmic drugs recited in claims 6 and 16.

Higuchi teaches an ocular therapeutic system, wherein suitable active agents are pilocarpine and pyrimethamine (Col. 11-12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute said particular ophthalmic drugs for the drug of Neefe with a reasonable expectation of success because the prior art suggests that said drugs are well-known for the purpose of treating the eye and can be used for ocular drug delivery.

9. Claims 2-3, 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neefe (US 3,786,812), Ding (PSTT, Vol. 1, No. 8, Nov 1998), Nagarsenker et al (Int. Journal of Pharmaceutics 190 (1999) 63-71), Evitts et al (EP 0 480 690), as applied to claims 1, 5, 7-9 and 20 above, and further in view of Seijo et al (Int. Journal of Pharmaceutics, Vol 62, Issue 1, 15 July 1990, abs)

As taught above Neefe/Ding/Nagarsenker and Evitts teach all the limitations of claim 1, but do not teach the nanoparticles to have a size of less than 50nm.

Seijo teaches the design of nanoparticles having a diameter of less than 50nm. These nanoparticles are used for drug release systems. Drug release from the particles was homogeneous and the particles were found to efficiently absorb both hydrophilic and hydrophobic drugs.

Based on the teachings of Seijo, one of skill in the art would recognize that the nanoparticles of Neefe and Ding could be prepared to have a diameter of less than 50nm. One of skill in the art would have a reasonable expectation of success, as these nanoparticles efficiently adsorb both hydrophilic and hydrophobic drugs and can be used for drug delivery systems.

It would have been obvious to one of skill in the art to optimize the size of the nanoparticles dependent on the desired purpose and desired results, as taught by Ding, absent any evidence of criticality. Furthermore it would have been obvious to one of skill in the art to distribute the nanoparticles in such a manner that optical transparency is maintained.

Regarding claims 3 and 21: Claims 3 and 21 claim that the amount of nanoparticles is from about 1-5% and from 5-20%. It would have been obvious to one of skill in the art through routine experimentation to determine the amount of nanoparticles necessary to achieve desired results, while maintaining the optical transparency of the contact lens.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER BERRIOS whose telephone number is (571)270-7679. The examiner can normally be reached on Monday-Thursday: 6:30am-3:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Berrios/
Examiner, Art Unit 1613

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635